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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,250	09/15/2000	David G. Matsuura	18608-001910	3797

7590  
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07/11/2003

EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	<b>Application No.</b> 09/663,250	<b>Applicant(s)</b> MATSUURA ET AL.	
	<b>Examiner</b> D Jacob Davis	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 4, 7, 9, 12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.                      6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Into an interior portion *thereof*" is indefinite. Does "thereof" refer to the interior portion of the mesh or the end?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 8 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Kotula et al. (US 5,846,261). Kotula discloses a method of sealing a hole comprising "introducing a generally cylindrical shaped mesh [Fig. 23] into the hole," (The hole refers to a septal defect.) An insertion tool is used to push the mesh proximal end through a catheter and into the hole (Col. 11, lines 63-65; Figs.10-11). While in the

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catheter, the mesh is in an elongated and radially compressed state (Col. 9, lines 20--et seq.). When released from the catheter into the septal defect, the mesh springs into position, causing the length to contract and the diameter to expand. As the insertion tool is pushes mesh into position, inherently, part of the proximal end of the mesh will be pushed distally within itself and will tend to expand the diameter once outside of the catheter.

Fig. 21 illustrates a different mesh embodiment inside of the septal defect showing bulges around the perimeter of the hole and in ingress prevention element, which is the body of the device. Regarding claim 6, the proximal end may be called the distal end and a distal direction may be called the proximal direction.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Leschinsky (US 5,904,713). Leschinsky discloses a method of "sealing" a hole in a body comprising introducing a cylindrically shaped mesh 8 and 9 into a hole and pulling the distal end 8 of the mesh through an interior portion of itself (proximal end 9). The distal end 8 is simply inverted within the distal end 9. The hole is "sealed" in that the device is constricted about the perimeter of the passage.

### ***Allowable Subject Matter***

Claims 10 and 11 are allowed.

Claims 4, 7, 9, 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***


Examiner agrees that Kensy does not disclose, "moving one of the cylindrical shaped mesh at least partially into an *interior portion* of the cylindrical shaped mesh."


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
DJD  
July 9, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700